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JUN 18 2019

CLERK U.S. DISTRICT COURT  
WEST. DIST. OF PENNSYLVANIA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA

*ex rel.* [SEALED],

Plaintiff,

- against -

[SEALED],

Defendants.

Civil Action No.: 19-720

FALSE CLAIMS ACT  
COMPLAINT

**[FILED UNDER SEAL]**

**FILED IN CAMERA AND UNDER SEAL PURSUANT TO  
31 U.S.C. § 3730(b)(2)  
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UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,  
*ex rel.* JAMES STEVEN BURDICK, M.D.,

*Plaintiff,*

v.

BOSTON SCIENTIFIC CORPORATION and  
XLUMENA, INC.,

*Defendants.*

Civil Action No.: \_\_\_\_\_

FALSE CLAIMS ACT  
COMPLAINT

**[FILED UNDER SEAL]**

*Qui tam* plaintiff and Relator James Steve Burdick, M.D., through his undersigned attorneys, hereby brings this action on behalf of the United States of America against Boston Scientific Corp. and Xlumena, Inc. The claims asserted in this Complaint are based on the facts and information set forth below and upon information and belief, unless otherwise stated.

**NATURE OF THE ACTION**

1. Relator sues Defendants to recover treble damages and civil penalties on behalf of the United States of America for their several schemes to maximize income from the sale of their AXIOS Stent family of products by causing the submission of false claims for payment to

Medicare, Medicaid, TRICARE, and other federally funded government healthcare programs (hereinafter referred to as “Government Healthcare Programs”).

2. Defendants knew they did not meet the established criteria set by the various Government Healthcare Programs and other applicable laws and regulations.

3. Defendants engaged in these widespread frauds against the United States in violation of the False Claims Act, 31 U.S.C. § 3729 *et seq.* (“FCA”).

4. As a highly accomplished interventional gastroenterologist, Relator has personally observed, and continues to observe, Defendants engage in practices in violation of the False Claims Act. These violations make it impossible for Defendants, and the billing entities that utilize Defendants’ defective products, to satisfy Government Healthcare Programs’ requirements for proper billing for the devices and the interventional gastroenterology procedures for which they are used.

5. Medical stents are small tube-like devices that can be inserted into the body to facilitate access between different body parts and organs so as to improve blood flow or to provide access for doctors to perform interventional procedures.

6. Cardiovascular stents which can be inserted into a vein or artery to improve blood flow and save lives might be the category most familiar to the average patient.

7. Other types of stents are functionally similar devices that can be used in other parts of the body. Often, they are used to provide access to difficult or impossible-to-reach organs and structures, allowing physicians to treat and remedy a variety of maladies.

8. At issue here is the Axios family of stents and stent delivery systems which are FDA approved and marketed for the treatment of certain disorders of the pancreas.

9. In reality, the Axios family of devices are used not only for the pancreas, but more broadly to treat a range of off-label maladies throughout the various gut organs including in the gallbladder.

10. The Axios stent and delivery system was purchased by Boston Scientific in 2015 when Boston Scientific acquired Xlumen.

11. Unfortunately, since Boston Scientific acquired the Axios family of devices, it has been manufacturing a large percentage of the devices with a dangerous latent defect.

12. Although the stent is FDA approved and marketed as a fully covered stent, Defendants have been selling and distributing stents with defective coverings.

13. As a result, patients are exposed to increased serious risks. These risks include a host of adverse events including bleeding, leaking, severe infection, tissue in- and over-growth, broken stents remaining in the body, and on more than one occasion, death.

14. Because of the way the Axios delivery systems were designed, the defective stent coverings are hidden from the physician until after the device has already been deployed inside a patient's body.

15. Defendants have known about the defects since at least 2016 when Relator personally advised Defendants and FDA of the defects.

16. Despite being so warned, Defendants have continued to produce, market, and sell the dangerously defective stents.

17. In fact, as described in greater detail below, instead of taking remedial steps to fix their dangerous product, Defendants instead submitted a materially false and fraudulent report to a government-maintained database. This false report to the government claimed the Axios device performed well and that there were **no** defects. Significantly, this false report was made to the government after Boston Scientific was specifically notified by Relator that the Axios products were defective. Indeed, Defendants' report to the government was the exact opposite of what Relator reported to Defendants.

18. Each claim for payment to the government for an Axios device generates many thousands of dollars of revenue for Defendants.

19. Each stent sold by Defendants must be implanted in, and later removed from, a patient's body. These procedures generate many tens of thousands of dollars of additional false claims caused by Defendants.

20. Furthermore, the adverse events caused by Defendants' defective devices naturally generate additional expenses and false claims.

**I. Parties**

**A. Relator – Dr. Burdick**

21. Relator James Steven Burdick, M.D. resides in Dallas County, Texas. From 2006 to the present he has had medical staff privileges at Baylor University Medical Center (“BUMC”). Dr. Burdick continues to see and treat patients at BUMC.

22. Dr. Burdick is an award winning and internationally renowned gastroenterologist and endoscopist.

23. After graduating from Oklahoma School of Medicine and completing an internal medicine residency at the Medical College of Wisconsin where he was the Chief Resident, Dr. Burdick completed gastroenterology and therapeutic endoscopy fellowship training at the Medical College of Wisconsin, Milwaukee and Racine campuses.

24. Dr. Burdick has been licensed to practice medicine in Wisconsin, Illinois, and Texas.

25. He is board certified in Gastroenterology and held many academic appointments over his long career.

26. Since 2007, he has been included in the annual “Best Doctors in America” list and, in 2017, Dr. Burdick was awarded the American Gastroenterology Association Distinguished Clinician Award.

27. He received the Physician of the Year award while on staff at the University of Texas Southwestern Medical Center where he also served as the Director of Endoscopy, Director

of Fellowship Training, Director of Gastroenterology at Parkland Hospital and Quality Assurance Director for Gastroenterology.

28. Dr. Burdick has published numerous peer-reviewed articles and abstracts, authored several book chapters, and given many national presentations.

29. Dr. Burdick is nationally recognized as having materially advanced the field of gastroenterology.

30. He has invented, perfected, or improved multiple procedures, techniques, and tools. Dr. Burdick was the first in the United States or the world to perform some of these procedures.

31. One of the endoscopic techniques Dr. Burdick invented has been named “Burdick’s Technique.”

32. Dr. Burdick was the first in the United States to:

- (a) perform a Zenker’s myotomy;
- (b) perform ablation of cholangiocarcinoma with an investigational device; and
- (c) use endosponge therapy for upper GI tract disease.

33. Dr. Burdick was the youngest director of fellowship for gastroenterology in the United States.

34. Dr. Burdick served as an expert for the prosecution in connection with the death of Michael Jackson.

35. Dr. Burdick has also had a long history of caring for patients without regard for their ability to pay for his services.

36. Mother Teresa and the Sisters of Charity recognized his charity work by awarding him the Sisters of Charity Recognition Award in December 1995.

37. Currently, Dr. Burdick is the Program Coordinator of the San Antonio Military Medical Center Gastroenterology Program.

38. Dr. Burdick's specialty is performing interventional or therapeutic endoscopy.

39. In other words, he inserts special endoscopes (or, more simply, "scopes") into the bodies of patients to perform a variety of minimally invasive procedures.

40. While Dr. Burdick does perform some routine esophageal and colorectal diagnostic procedures, what sets him apart from his peers is his ability to use scopes to perform natural orifice transluminal endoscopic surgery, therapeutic endoscopy, Endoscopic Ultrasound ("EUS"), and Endoscopic Retrograde Cholangiopancreatography ("ERCP"). These specialized procedures are used to treat a variety of more complicated and difficult-to-manage conditions like life-threatening gallbladder and pancreas infections and stones.

41. In addition, these advanced procedures can be used to treat various bleeding conditions along and within the gastrointestinal ("GI") tract. These procedures are not only performed by Dr. Burdick, but in some cases, he was the doctor responsible for pioneering and perfecting them.

42. For example, in patients with certain liver diseases, it is possible for small blood vessels in the stomach and esophagus to swell and rupture, creating a life-threatening bleed. Without emergent treatment, these patients will bleed to death. Dr. Burdick is uniquely qualified to perform some of those life-saving treatments.

43. Not all GI doctors – or even endoscopy-trained GI doctors – are able to perform the same breadth and extent of procedures as Dr. Burdick.

44. For this reason, Dr. Burdick has received referrals from nearly 600 unique physicians over the last two years alone. And in 2018 he performed more than 50% of all advanced GI procedures done at BUMC.

45. He is also routinely called upon to assist other services within BUMC to treat their most critical and hardest-to-manage patients, and is often called on to do so on an emergency basis.

46. For example, the liver transplant team at BUMC routinely calls on Dr. Burdick to perform therapeutic endoscopy to fix various complications like biliary leaks and bypass obstructions.

47. By letter dated August 9, 2018, Relator provided notice to the United States Attorney General, the United States Attorney for the Northern District of Texas, and the Attorney General of the State of Texas regarding the fraud at issue here. Relator also provided notice of these frauds to the United States Attorney's Office for the Western District of Pennsylvania via an April 22, 2019 meeting and June 12, 2019 letter.

**B. Boston Scientific Corp.**

48. Boston Scientific Corp. is a Delaware Corporation that regularly conducts business in the Commonwealth of Pennsylvania.

49. Boston Scientific is a large medical device manufacturer and seller.

50. Boston Scientific reported net sales of nearly \$10 billion in 2018 with profits in excess of \$7 billion.

51. Boston Scientific operates through various subsidiaries and controlled entities.

**C. Xlumena, Inc.**

52. Xlumena, Inc. is a Delaware registered corporation and a subsidiary of Boston Scientific Corp. and upon information and belief regularly conducts business in the Commonwealth of Pennsylvania.

53. Xlumena was acquired by Boston Scientific in or about August 2015 and has since operated as a subsidiary of Boston Scientific.

54. Before the August 2015 acquisition, Xlumena invented and then manufactured and sold Axios devices.

55. In fact, a portion of the transaction price for Boston Scientific's acquisition of Xlumena was contingent on receipt of FDA approval for the "Hot" Axios device.

56. Since the 2015 acquisition, Xlumena continues to make and sell Axios devices under the aegis of Boston Scientific.

57. Together, Defendants manufacture, market, and/or sell the Axios family of stents and stent delivery systems or own and control the entity or entities that do.

### **JURISDICTION AND VENUE**

58. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1345 because this action involves a federal question and the United States is a plaintiff. This Court also has subject matter jurisdiction under 31 U.S.C. § 3732(a).

59. The Court may exercise personal jurisdiction over Defendants under 31 U.S.C. § 3732(a). The Court has personal jurisdiction over Defendants because they regularly transact business within this District.

60. Venue is proper in this District under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b) & (c) because Defendants transact business or are found within this District and a substantial part of the events establishing the alleged claims arose in this District.

61. This Complaint is not based on a public disclosure as defined in 31 U.S.C. § 3730(e). Relator sues as the original source of information regarding Defendants' violations of the FCA, given that Relator has direct and independent knowledge of the information on which the allegations are based; and/or knowledge that is independent of and materially adds to any allegations or transactions which may have been publicly disclosed (although Relator knows of no such public disclosure).

62. No allegation in this Complaint is based on a public disclosure of allegations or transactions in a criminal, civil, or administrative hearing; in a congressional,

administrative, or General Accounting Office report, hearing audit, or investigation; or from the news media. Rather, Relator is the original source of the discovery of the wrongdoing alleged.

## **FACTS**

### **II. Governing Laws**

#### **A. The Federal False Claims Act**

63. Originally enacted in 1863, the FCA was substantially amended in 1986 by the False Claims Amendments Act. The 1986 amendments enhanced the Government's ability to recover losses sustained because of fraud against the United States.

64. The FCA imposes liability upon any person who "knowingly presents, or causes to be presented [to the Government] a false or fraudulent claim for payment or approval," "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," or conspires to do so. 31 U.S.C. § 3729(a)(1). Any person found to have violated these provisions is liable for a civil penalty of not less than \$11,181 and not more than \$22,363 for each such violation, plus three times the damages sustained by the Government.

65. The FCA imposes liability where the conduct is "in reckless disregard of the truth or falsity of the information" and clarifies that "no proof of specific intent to defraud" is required. 31 U.S.C. § 3729(b).

66. The FCA also broadly defines a “claim” to include “any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that - ... is made to a contractor, grantee, or other recipient if the money or property is to be spent or used on the Government’s behalf or to advance a Government program or interest...” 31 U.S.C. § 3729(b)(2)(A).

67. The FCA empowers private persons having information regarding a false or fraudulent claim against the Government to sue on behalf of the Government and to share in any recovery. 31 U.S.C. § 3730(b).

#### **B. The Federal Health Benefit Program**

68. Medicare was created in 1965 by Title XVIII of the Social Security Act and is by far the largest health plan in the United States. Medicare Part A (the basic plan of hospital insurance) covers the cost of hospital inpatient stays and post-hospital skilled nursing facility care. 42 U.S.C. §§ 1395j to 1395w-4. Medicare Part B is a federally subsidized, voluntary insurance program that covers a percentage (typically 80%) of the fee schedule amount of physician and laboratory services. 42 U.S.C. §§ 1395k, 1395l, 1395x(s).

69. Medicare is generally administered by the Centers for Medicare and Medicaid Services (“CMS”), which is an agency of the Department of Health and Human Services. CMS establishes rules for, and contracts with private companies to handle, the day-to-day administration of Medicare.

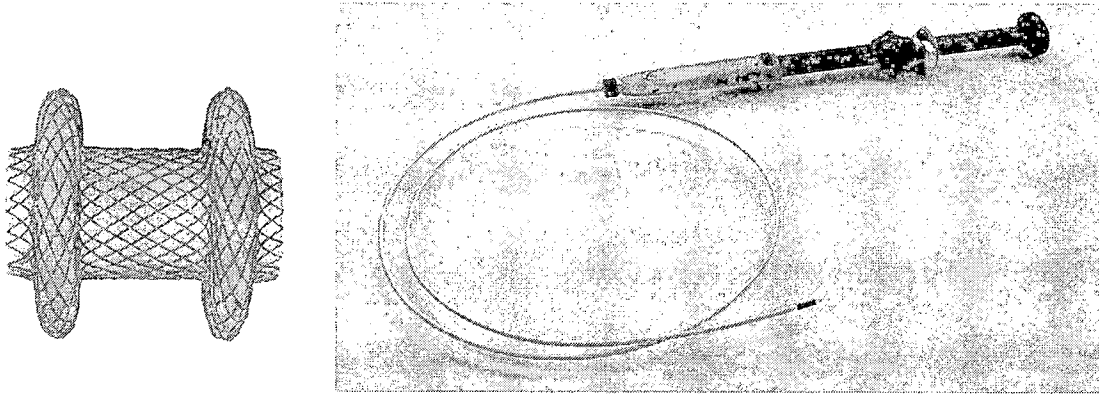
70. Medicare only pays for services or equipment that are reasonable and medically necessary. 42 U.S.C. § 1395y(a)(1)(A). Further, all providers enrolled in the Medicare program must provide economical medical services. 42 U.S.C. § 1320c-5(a)(1). Providers must assure that the services they provide are medically necessary and appropriate. *See* 42 U.S.C. § 1320c-5(a)(3). The funds used to pay Medicare Part A claims come both from federal payroll and general tax revenues. The funds to pay for Part B come from premiums paid by Social Security recipients and general U.S. tax revenues.

71. Medicaid is a joint federal-state program that provides healthcare benefits for certain groups: primarily the poor and disabled. States administer their own Medicaid programs under federal regulations that govern what services should be provided, and under what conditions. CMS monitors the state-run programs and establishes requirements for service delivery, quality, funding, and eligibility standards. The federal government provides a portion of each state's Medicaid funding, known as the Federal Medical Assistance Percentage ("FMAP"). The FMAP is based on the state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). State Medicaid programs must cover inpatient hospital services.

### **III. The Axios family of devices**

72. The Axios family of devices includes multiple fully covered flexible metal stents and their various self-contained deployment devices.

73. Boston Scientific renderings of an Axios stent and an Axios deployment device appear below. Until it is deployed inside the body, the stent is held in a folded or compressed state near the end of the thin white tube.



74. The Axios stents are FDA approved as fully covered stents and they are marketed and sold by Defendants as both fully covered and FDA approved.

75. Defendants sell the Axios stents in three sizes, 10mm x 10mm, 15mm x 10mm, and 20mm x 10mm,<sup>1</sup> and each stent is pre-loaded into its Axios delivery system.

76. Among other benefits, the Axios family of stents allow interventional gastroenterologists the ability to make temporary and semi-permanent artificial connections between the stomach and other gut organs like the pancreas, gallbladder, and similarly located digestive and internal organs.

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<sup>1</sup> These measurements give the internal diameter of the tube first, followed by the length of the stent. A 10mm x 10mm stent is approximately one-third of an inch by one-third of an inch, when fully deployed. When it is first inserted into the patient's body, it is compressed to a smaller size and sheathed inside the deployment device. After the physician cuts the hole(s) and deploys the stent, the device springs into its final shape and larger size and bridges the gap.

77. These artificial connections can be thought of as tunnels through the body.
78. Physicians use these tunnels to gain access to the internal organs through minimally invasive techniques. Doctors then manually remove or allow to drain various infections, stones, cancers, and necrotic and otherwise purulent matter from the organs reached through the stent.
79. Because the stents function like a tunnel transporting highly caustic, infectious, or otherwise harmful bodily contents, it is crucial the stents are fully covered.
80. When the stents are not fully covered, all of those dangerous materials can spill through the holes in the covering and into the peritoneal space (the space between the organs of the gut).
81. This spillage predictably and directly leads to very virulent and dangerous peritoneal infections, infections at the site of the stent, bleeding, and systemic infections. Ultimately, patient death can ensue.
82. In addition, defective stent covering permits the body's tissues to begin "healing over" and through the stent itself. This is known as tissue in- and over-growth.
83. Tissue in- and over-growth describes, as it sounds, the tissues of the patient growing around, over, and through the metal mesh of the stent, much like a tree grows around and through a chain-link fence.
84. This in turn leads to bleeding, infection, stent migration, and difficulty removing the stent.

85. Difficulty removing the stent can cause stents to break on retrieval. This, in itself, can lead to further potentially dangerous interventions including surgery, and puts the patient at significantly higher risk.

86. Several innovations are built into the Axios family of devices, including the relatively large diameter of the tunnel, the flanges on the sides which help to hold the stent in place inside the body, and the delivery system which permits placement of the stent using a single self-contained deployment device. The flexible metal mesh construction permits the stents to be compressed and folded into the deployment device which in turn enables the use of much larger stents.

87. The Hot Axios version of the stent incorporates an electrically powered heat-based cutting head at the working end of the deployment device.

88. The fact that the stent is supposed to be fully covered was not an innovation. Stents used in this part of the body must be fully covered in order to be effective. The fact that the stents are fully covered permits fluids and other materials to be drained from one organ to another without leaking and infecting other body parts.

89. The solid plastic stents that the Axios stents were replacing in the marketplace were single-piece stents which were not permeable.

**IV. Defendants cause fraudulent claims to be made by doctors and hospitals which use the Axios family of devices.**

**A. FDA and Medical Devices**

90. FDA regulates the use and sale of medical devices.

91. Under 21 CFR Part 860, FDA determines if medical devices are safe and effective.

92. Defendants, or their predecessors in interest, sought and received approval for the Axios family of stents and stent delivery systems.

93. The Axios stents were approved, and are marketed, as fully covered metal stents.

94. Defendants manufacture, promote, and sell the Axios family of stents and stent delivery devices as fully covered pancreatic drainage stents.

95. For certain procedures, an Axios stent is the only device appropriate and approved for use. But the Axios stents are considered appropriate, reasonable, and necessary only if they are in fact fully covered.

96. Defendants sell these devices to various healthcare providers nationwide, including the University of Pittsburgh Medical Center (“UPMC”) and BUMC. These healthcare providers then use the Axios devices in patients, including patients covered by Government Healthcare Programs.

97. Relator discovered that the Axios family of stents are not fully covered. Instead, they are riddled with holes, which make them defective and dangerous.

98. Despite knowing of these serious, material defects, Defendants continue to market and sell the defective stents for use in patients – including in patients covered by Government Healthcare Programs.

99. Defendants manufacture and sell devices which they know are defective and fail to meet the requirements set by FDA.

100. The use of these defective devices has caused avoidable adverse patient events, including death.

101. Nevertheless, Defendants continue to make, market, and sell defective devices.

102. When Axios stents are used in patients, Government Healthcare Programs are charged for the sale, use, and removal of the defective stents.

103. Government Healthcare Programs pay for these defective stents, for procedures attempted or completed using the defective stents, and for the follow up care made necessary by the defects.

**B. Dr. Burdick Finds the Defect**

104. Dr. Burdick performed a procedure using an Axios stent in May 2016 for a patient in severe distress.

105. The patient was suffering from cholecystitis, biliary colic, and cirrhosis and, without intervention, was certain to die over the coming days or weeks.

106. Surgery and medicine teams had run out of options.

107. It was agreed – by the doctors treating the patient and the patient himself – that the patient’s only and best chance at survival was for Dr. Burdick to perform an interventional endoscopic procedure to gain access to, and then drain, the patient’s gallbladder.

108. The procedure, techniques, and risks were discussed with the patient’s team of providers, the patient, and his family.

109. There was universal agreement that this was appropriate – the procedure is well supported by the literature – and was considered the only viable course of action for this particular patient. Dr. Burdick was well qualified to do it, and the patient gave his informed consent.

110. Unfortunately, after the procedure, the patient did not improve. Significantly, follow-up imagining confirmed proper stent placement, but revealed leaking around the stent location.

111. The patient was eventually taken for additional surgery which failed, and the patient died.

112. Dr. Burdick later discovered that the Axios stent used during the endoscopic procedure was defective.

113. The stent covering had multiple holes.

### **C. A Hidden Defect**

114. Following this surgery, Dr. Burdick retrieved or reviewed all similar stents that were used on other patients.

115. Although Defendants had obtained approval for a fully covered stent – and market the stent as fully covered – Dr. Burdick discovered that the coating around every stent he examined had holes.

116. The defects can be observed after stent retrieval and removal.

117. These defects are particularly dangerous because Defendants' product design makes it impossible to observe the defect before the stent is deployed and in use inside a patient's body. As a result, neither patients nor their doctors are able to protect themselves against these defects until it is too late.

118. Because the stents are sold and used in their pre-packaged ready-to-deploy configuration, it is not possible for physicians to examine the stents before they are used.

119. The endoscopic devices used to place Axios devices often include the ability to capture video and/or still images during the procedure.

120. A careful review of these images can sometimes reveal defects in the stent covering but only after the devices have been deployed.

121. As a practical matter, this means the doctor has already cut a hole between two organs inside the body and deployed the stent to bridge and plug the gap before any part of the stent covering is visible.

122. But, even then, only approximately 1/3 of the stent covering is ever visible when the stent is inside the body and the remaining 2/3 of the stent remains hidden from view until the stent is removed.

123. It was Dr. Burdick's subsequent review of the images from the deceased gallbladder patient's procedure that revealed the holes in that particular stent. Prior to Dr. Burdick's investigation of the cause of that patient's death, he had no reason to suspect there was anything wrong with the Axios stent covering. After all, it had been approved by FDA and marketed by Boston Scientific as a fully-covered stent.

124. After this patient's death, Dr. Burdick consulted with the nation's leading experts about the procedure, and together they concluded that the holes that had been posthumously revealed had allowed bile to escape into the patient's body, causing infection and death. In short, a defect in the stent – holes in the covering – had caused the patient's death.

**D. Dr. Burdick reports the defects to FDA and Boston Scientific.**

125. Dr. Burdick reported the problem with the holes in the stent – along with the adverse patient outcome – to Boston Scientific and FDA.

126. Dr. Burdick was the first person to report these defects to FDA.

127. Because Defendants had hid and failed to warn doctors and FDA about these defects, the defects were unknown to, and undiscoverable by, Dr. Burdick before this particular patient's procedure.

128. Due to Dr. Burdick's discovery and responsible reporting, FDA convened meetings, studied the issue, and eventually followed up with Boston Scientific to address the defects Dr. Burdick found.

129. But, instead of remedying the defects, Defendants undertook to hide them and continue to sell materially defective stents even to this day.

130. For his part, Dr. Burdick has stopped using the Axios stents in patients for whom the integrity of the covering is most important. In addition, he has implemented a rapid withdrawal protocol for all of his patients whereby he removes Axios stents within days or weeks of initial deployment.

**E. Boston Scientific submitted fraudulent entries to the MAUDE database.**

131. Device manufacturers are generally required to report adverse events through FDA's MAUDE (Manufacturer and User Facility Device Experience) Database. *See gen.* 21 C.F.R. § 803, Subpart E – Manufacturer Reporting Requirements.

132. Boston Scientific appears to be both under-reporting and misreporting adverse events in the MAUDE Database.

133. An adverse event related to the gallbladder patient Dr. Burdick treated in 2016 did appear in the MAUDE Database.

134. But it was reported as “no known device problem.”

135. In or about the summer or fall of 2016, Dr. Burdick again contacted Boston Scientific, this time to report that he *had* identified holes in the stent used on the deceased gallbladder patient. Moreover, Dr. Burdick informed Boston Scientific that in every other stent that he used at BUMC – and which Dr. Burdick had examined subsequent to the patient's death – there were holes in the coverings.

136. Shockingly, on or about September 8, 2016, Boston Scientific “updated” this MAUDE entry to add that “no holes were identified in the stent ... The physician confirmed that he did not identify any holes in the stent used in that procedure.”

137. *The exact opposite is true.*

138. This MAUDE entry remains listed as “no known device problem.”

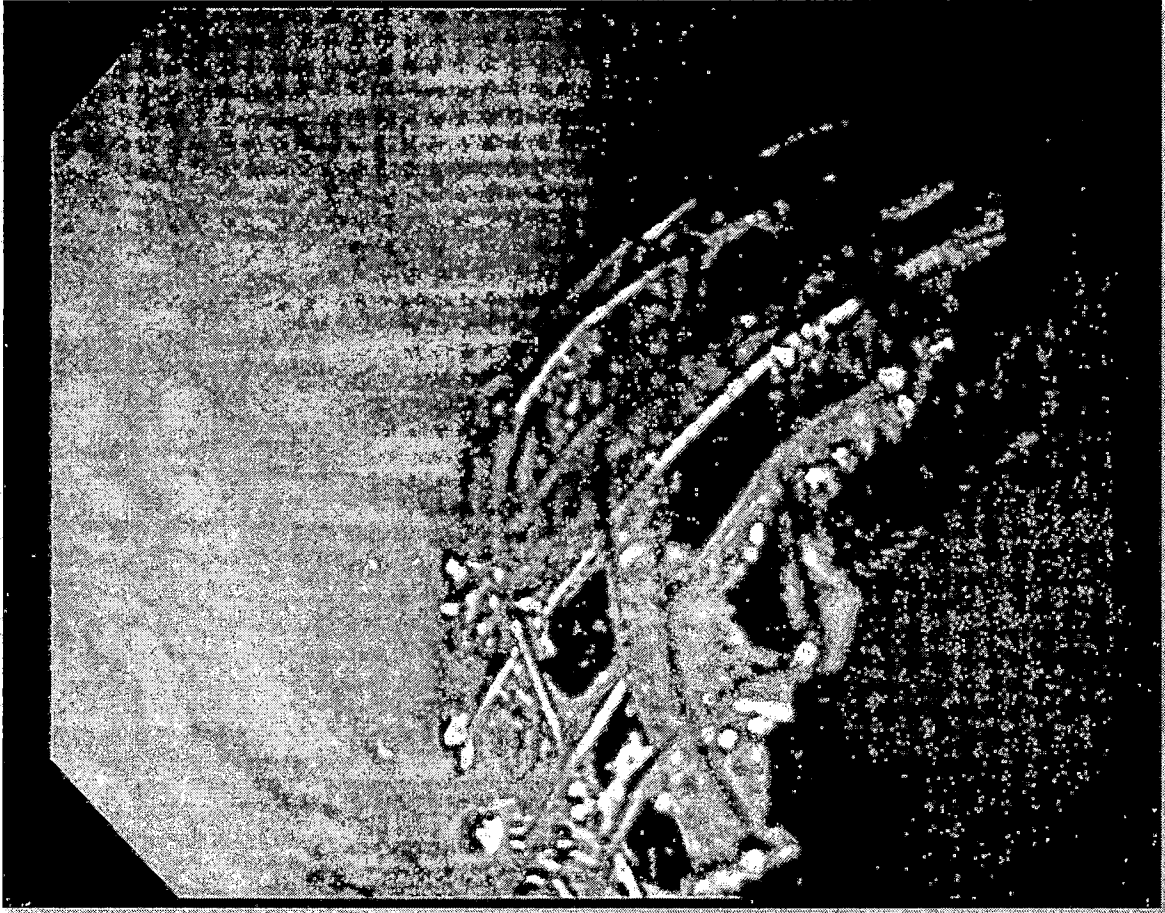
**F. Defendants continue to sell defective stents.**

139. Subsequent to the patient’s death, Dr. Burdick began to examine every stent he used. Terrifyingly, at the time of this patient’s death, every stent Dr. Burdick reviewed was defective. From 2016 until 2018, virtually every stent Dr. Burdick examined had holes in the covering. Since 2018, the defect rate appears to have fallen to a still unacceptable rate of approximately 20-50%.

140. Shockingly, even after Dr. Burdick reported the defective stents to Boston Scientific and after FDA followed up with Boston Scientific, Dr. Burdick continued to observe defective stents being sold to BUMC and other healthcare facilities, and being used on patients.

141. Dr. Burdick continues to find dramatic defects in the stents to this day.

142. The below picture is a stent with many defects (holes in the covering between the wire frame) which was found on or about December 22, 2018.



## **CAUSES OF ACTION**

### **COUNT I – VIOLATION OF 31 U.S.C. § 3729(a)(1) (All Defendants)**

143. Relator repeats and re-alleges the allegations set forth in the preceding paragraphs, as if fully set forth herein.

144. The False Claims Act, 31 U.S.C. § 3729(a)(1)(A), imposes liability upon those who knowingly present or cause to be presented false claims for payment or approval.

145. Defendants knowingly caused to be presented false or fraudulent claims for payment or approval to the United States for the use of defective Axios devices that were not reasonable and necessary and therefore were not reimbursable by the relevant Government Healthcare Programs.

146. Specifically, for at least the last four years, Defendants caused medical bills to be submitted to Government Healthcare Programs, including Medicare and Medicaid, seeking payment for both defective devices as well as devices that did not comply with the requirements set by FDA.

147. Defendants similarly caused medical bills to be submitted to Government Healthcare Programs, including Medicare and Medicaid, seeking payment for services rendered in connection with the use and retrieval of both defective devices as well as devices that did not comply with the requirements set by FDA, as well as the adverse events caused thereby.

148. Defendants knew or should have known (as defined in 31 U.S.C. § 3801(a)(5)) that they had for years caused to be made false or fraudulent claims for payment to Government Healthcare Programs.

149. Each of the claims caused to be submitted by Defendants is a separate false and fraudulent claim.

150. Defendants caused to be presented these claims knowing their falsity, or in deliberate ignorance or reckless disregard that such claims were false.

151. The United States was unaware of the foregoing circumstances and conduct of Defendants and, in reliance on said false and fraudulent claims, authorized payments to be made on the false claims Defendants caused to be made, made such payments, and has been damaged.

152. Because of these false or fraudulent claims caused to be submitted by Defendants, the United States has been damaged in an amount to be determined at trial.

**COUNT II – VIOLATION OF 31 U.S.C. § 3729(a)(1)(C)**  
**(All Defendants)**

153. Relator repeats and re-alleges the allegations set forth in the preceding paragraphs, as if fully set forth herein.

154. The False Claims Act, 31 U.S.C. § 3729(a)(1)(C), imposes liability upon those who conspire to commit a violation of another sub-section of the False Claims Act.

155. Defendants knowingly, in reckless disregard, and/or in deliberate ignorance of the truth conspired between themselves, with their employees and administrators, and others, to violate the False Claims Act.

156. Defendants conspired to cause to be submitted false and fraudulent claims related to the provision and use of defective Axios devices.

157. Defendants did in fact cause the submission of false and fraudulent claims for the provision and use of defective Axios devices.

158. As a consequence of their conspiracies, the United States paid these claims when it would not have but for Defendants' unlawful conduct.

159. As a result of these conspiracies, and the resulting false or fraudulent claims submitted or caused to be submitted by Defendants, the United States paid the claims, resulting in damages to the United States in an amount to be determined at trial.

#### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff-Relator demands and prays that judgment be entered against Defendants, jointly and severally, as follows:

- A. ordering that Defendants cease and desist from violating the False Claims Act, 31 U.S.C. § 3729 *et seq.*;
- B. directing that each Defendant pay an amount equal to three times the amount of damages the United States has sustained because of such Defendant's actions;
- C. directing that each Defendant, pursuant to the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, pay penalties of not less than \$11,181 and not more than \$22,363 for each such Defendant's violation of the False Claims Act;
- D. granting Relator the maximum amount allowed under 31 U.S.C. § 3729, and/or any other applicable provision of law;
- E. directing that each Defendant, jointly and severally, pay Plaintiff-Relator's fees and costs, including attorneys' fees, as provided by the False Claims Act;

- F. directing that each Defendant pay interest on all sums ordered paid;
- G. ordering that Relator recover such other relief as the Court deems just and proper; and
- H. granting such other and further relief as the Court deems just and proper.

**REQUEST FOR TRIAL BY JURY**

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby requests a trial by jury.

Dated: June 18, 2019  
Pittsburgh, PA

POLLOCK COHEN LLP

By:

A handwritten signature in black ink, appearing to read 'Darth M. Newman', written over a horizontal line.

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